UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,470	08/24/2001	Robin Edwin Buckingham	P31853C1	3823

7590 09/10/2003

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER
CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
1617	7

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,470	BUCKINGHAM ET AL.	
	Examiner	Art Unit	
	Theodore J. Criares	1617	

-- Th MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

CLAIMS 23-93 ARE PRESENTED FOR EXAMINATION

Applicant's arguments filed May 22, 2003 have been fully considered but they are not persuasive.

Applicants argue that a prima facie case is not presented by the examiner for the following reasons:

1. there is a lack of motivation to select the claimed dosages of compound (I) to be used in combination with gilimepiride and metformin to treat diabetes mellitus and conditions associated therewith, specifically type II diabetes;

2. there is a lack of guidance or a basis for expectation of success that compound (I) can be used, in combination with gilimepiride and metformin, in the amount of 2-12 mg per day to treat diabetes mellitus and conditions associated therewith, specifically type II diabetes;

3. that there is a failure to disclose or suggest that compound (I) can be used in the amount of . of 2-12 mg per day to treat diabetes mellitus and conditions associated therewith, specifically type II diabetes; and

4) that there is a lack of disclosure or suggestion to administer Compound (I) in the amount of 2-12 mg per day to treat diabetes mellitus and conditions associated therewith, specifically type II diabetes;

The applicants admit at page I of the specification that each of the compounds claimed in the present application ave the ability to regulate hyperglycemia. A reading of U.S.Patent to Ideda et al. (5,952,356) teaches at column 15, lines 2-15 that compound (I) can be administered to treat

hypergycemia in an amount of from 0.1 to 1500 mg. Applicants' claims to the amount of compound I to be used are within the of range claimed by applicants.

Therefore, applicants' arguments 1-3 are obviated since applicants' claimed active agents each are known to treat hyperglycemia,. This includes diabetes Type II. It would be obvious under 35 UCC 103 (a) to combine the active agents as stated as stated in In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

> '"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-277, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art. "

In this application it would have been prima facie obvious to administer t o treat diabetes mellitus and Type II diabetes since the claimed compounds have the same characteristics, they are known to treat hyperglycemia.

There is a lack of data in the specification to support applicants' arguments that the amounts and the number of times per day are critical.

In view of the above the rejection set forth in the previous Office Action is deemed proper.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Further, in view of the above claims 23-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicants admissions in view of Ikeda et al.

The applicants' admit that the claimed compounds have the same property, i.e., they are anti-hyperglycemic agents. The difference between applicants' claims and the prior art is the specific amounts of Compound I which is required. However, the skiled artisan would have been motivated to use applicants' claimed amounts since Ikeda, as stated above, teaches arrange in which the compound I will be effective. It would require only routine skill in the art by the skilled artisan to determine the optimum or workable ranges. See In re Aller et al. 105 USPQ 233.

The above is a new rejection in addition to the previous rejection.

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to

Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Theodore J. Criares
Primary Examiner
Art Unit 1617

tjc
September 8, 2003